11-16-05

AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTEREFERENCES

In re Application of:	§	
	§	
PETER T. O'HEERON	§	Group Art Unit: 3728
	§	
Application No.: 10/646,675	§	Examiner: David Fidei
	§	
Filed: 08/22/2003	§	
	§	
For: Medical Procedure Kit	§	

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CERTIFICATE OF EXPRESS MAILING
37 C.F.R. § 110

I hereby certify that this Amended Brief on Appeal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on November 15, 2005, in an envelope marked as "Express Mail United States Postal Service", Mailing Label No. EO914372868US, addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature

Sharon Goodson
Name

11/15/2005
Date of signature

AMENDED BRIEF ON APPEAL

Pursuant to 37 C.F.R. § 1.192, Assignee NeoSurg Technologies, Inc. files this amended brief in triplicate in support of its appeal from the final rejection mailed August 9, 2005 in the above-identified patent application. The requisite appeal fees have already been paid.

I. REAL PARTY IN INTEREST

The Real party in interest in this application and appeal is NeoSurg Technologies, Inc., 17300 El Camino Real, Suite 110, Houston, Texas 77058, Assignee of the above-identified application.

II. RELATED APPEALS AND INTERFERENCES

Neither the Assignee nor the Assignee's legal representatives know of any other appeal or interference which will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Dependent claims 8, 9 and independent claim 18 are the claims on appeal and are set forth fully in Appendix A to this brief. A final rejection of claims 8, 9 and 18 was mailed on August 9, 2005.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final rejection of August 9, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. The Technology to Which Independent Claim 18 Pertains

The invention of claim 18 generally relates to a surgical instrument known as a trocar which is used in endoscopic surgery to pierce or puncture an anatomical cavity to provide communication with the cavity during a surgical procedure. Specification, p. 1, ln. 8-10. In particular, the present invention relates to a medical procedure kit comprising one or more obturators designed for use with a trocar. Specification, p. 3, ln. 13-14.

Endoscopic surgery constitutes a significant method today of performing surgeries and is the surgical procedure of choice because of the patient care advantages over "open surgery." One form of endoscopic surgery is laparoscopic surgery, which usually has a post-operative recovery time which is substantially less than the recovery time associated with open surgeries. Additionally, laparoscopic surgery achieves decreased incidents of post-operative abdominal adhesions, decreased post-operative pain and enhanced cosmetic results. Specification, pp. 1-2.

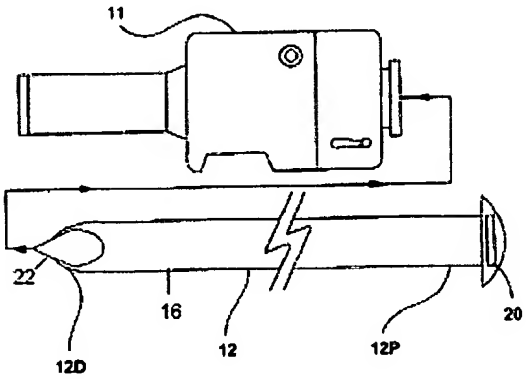
A trocar may be used in a laparoscopic surgical procedure to penetrate the abdominal wall once the abdominal cavity has been insufflated with carbon dioxide. Specification, p. 2, ln. 4-9. A trocar includes a body assembly, a cannula assembly which is attached to the body assembly to form a bore through the body assembly, and a piercing element called an obturator. *Id.* The obturator slides in the bore of the trocar and has a piercing tip at its end. After insertion of the trocar through the abdominal wall of the patient, the obturator is removed by the surgeon while leaving the cannula protruding through the body wall. Laparoscopic instruments can then be inserted through the cannula to view internal organs and to perform surgical procedures. Specification, p. 5, ln. 10-15.

B. The Subject Matter Defined in Independent Claim 18

Independent claim 18 is directed to a medical procedure kit is comprising at least one disposable, shield-less obturator for use in endoscopic surgery. Specification, p. 3. Claim 18 specifies that each such obturator comprises proximal end (12P) and a distal end (12D) with a shaft (16) between those ends. Specification, p. 4, l. 18-p. 5, l.1; FIGS 1

and 3. The proximal and distal ends and the shaft are formed as a monolithic member. Specification, p. 5, ln. 3-5; FIGS 1 and 3. As specified in claim 18, the obturator is grasped at the proximal end (12P) and the distal end (12D) has a tip which is used either to cut or to separate tissue of a patient. Specification, p. 5, ln. 10-13; FIGS. 1 and 3.

Significantly, each obturator as defined by claim 18 includes an orientation indicator (20) located near the proximal end (12P) which enables a user to determine by touch the relative position of the tip at the distal end. Specification, p. 6, ln. 1-10; FIGS. 2-3. As illustrated in FIG. 3 reproduced below (with reference designators 16 and 22 added), the handle of the obturator is equipped with one or more raised surfaces or indentations 20 which correspond to the relative position of the tip 22 with respect to the shaft 16. *See also* Specification, p. 6, ln. 1-10.



For example, a surgeon would know, by touching the orientation indicator 20 as illustrated in FIG. 3 above, that the orientation of the tip was as shown in FIG. 3.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The rejection of claims 18 and 8 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,405,328 to Vidal ("Vidal patent").

2. The rejection of claims 18 and 8 under 35 U.S.C. § 103 as unpatentable over the Vidal patent.

3. The rejection of claims 18 and 9 under 35 U.S.C. § 103 as being unpatentable over the combination of U.S. Patent No. 5,118,297 to Johnson ("Johnson patent") and U.S. Patent No. 5,453,094 to Metcalfe ("Metcalfe patent").

VII. ARGUMENT

A. Standard for Establishing Anticipation

For a prior art reference to anticipate, every element of the claimed invention must be identically shown in a single reference, and the elements in the reference must be arranged as in the claim under review. *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990); *see also C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1349 (Fed. Cir.), *rehearing denied and suggestion for rehearing en banc declined,* 161 F.3d 1380 (Fed. Cir. 1998); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987), *cert. denied,* 484 U.S. 1007 (1988). Anticipation of the claim can only be found where the prior art reference shows **exactly** what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780-782 (Fed. Cir. 1985).

B. Standards With Respect to Establishing a *Prima Facie* Case of Obviousness

Three criteria must be established in order to make out a *prima facie* case of obviousness based on a combination of prior art references. First, there must be some suggestion or motivation, either in the references used by the Examiner or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference or references, when combined, must teach or suggest all of the claimed limitations. *See* M.P.E.P. § 2143; *see also In re Vaeck,* 947 F.2d 488, 493 (Fed. Cir. 1991).

Before the conclusion of obviousness of a patent claim can be made based on a combination of references, there must have been a suggestion or motivation to lead an inventor to combine those references. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed. Cir. 1984); *see also Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1327 (Fed. Cir. 2001) (judgment upholding validity of patents in suit affirmed in absence of suggestion, motivation or teaching to combined the prior art); *Jazz Photo Corp. v. U.S. Int'l Trade Comm'n,* 264 F.3d 1094, 1109 (Fed. Cir. 2001) (In absence of a suggestion to combine prior art references, the patented process was not rendered obvious); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001); *WMS Gaming, Inc. v. Int'l Game Technology,* 184 F.3d 1339, 1359 (Fed. Cir. 1999); *In re Dance,* 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). The teaching or suggestion to make the claimed combination must be found in the prior art, not in the applicant's disclosure. *Vaeck*, 947 F.2d at 493.

Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996).

If the proposed modification or combination of the prior art would change the principle of the operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). In *Ratti*, the claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers

inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. The reference disclosed that the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.

A critical step in analyzing the patentability of claims pursuant to section 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *In re Dembiczak,* 175 F.3d 994, 999 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of the hindsight syndrome wherein that which only the invention taught is used against its teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.,* 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert denied,* 469 US 851 (1984).

C. The Examiner's § 102 and § 103 Rejections of Claim 18 Based on the Vidal Patent are Erroneous

1. Two Reasons Exist to Reverse the § 102 Rejection Based on Vidal

As noted above, claim 18 of the present application calls for "an orientation indicator located near the proximal end [of the obturator] which enables a user to determine by touch the relative position of the tip at the distal end [of the obturator]." According to the Examiner:

> As shown in figures 15 and 16 of Johnson [*sic*-Vidal] handle 202 includes an abrupt disc part of larger diameter than shaft 201 adjacent the proximal end. This change in diameter manifestly serves as an orientation indicator extent claimed where a user can determine by touch the relative position of the tip at the distal end. Office Action, p. 4.

The Examiner's conclusion quoted above is simply erroneous, because the change in diameter between the shaft of proximal end 201 and handle 202 in the obturator disclosed in the Vidal patent does not provide any information to the user about the orientation of the tip at the distal end of the obturator. The difference in diameter between the shaft of proximal end 201 and handle 202 is virtually the same at all points, and the only "information" that can be obtained from this difference is that a change in diameter exists. Significantly, the Vidal patent does not describe the change in diameter cited by the Examiner as any sort of indicator of the orientation of the tip.

In sharp contrast, the orientation indicator in applicant's invention allows the user to determine by touch the orientation of the tip at the distal end of the obturator. For example, the embodiment illustrated in FIG. 3 of the present application, the user knows

by touching indicator 20 that the orientation of the tip of the obturator is as shown in FIG. 3 and that the tip is not rotated 90° from the position shown in FIG. 3.

Thus, since the Vidal patent does not describe an orientation indicator as called for by claim 18, the Examiner's § 102 rejection of claim 18 based on Vidal is reversible on that ground alone.

Moreover, a second difference between claim 18 and Vidal exists which also compels the reversal of the Examiner's § 102 rejection of claim 18 based on Vidal. Claim 18 specifies that the proximal and distal ends and shaft of the obturator are formed as a monolithic structure, and the Vidal patent does not describe such a monolithic structure.

The Examiner no doubt recognized that Vidal did not disclose a monolithic structure and avoided addressing that fact by arbitrarily deciding that the limitation "monolithic" in claim 18 does not exist. According to the Examiner, the limitation "monolithic" in claim 18 is "considered a product by process type of limitation of no patentable moment." Office Action, p. 4. The only authority cited by the Examiner to support this autocratic position are cases holding that the patentability of a product by process claim is determined without consideration of the process used to make the product. *Id.* at n. 1. Since claim 18 of the present application does not recite any process steps, the Examiner's reliance on those cases is misplaced. The Examiner's action in disregarding the limitation "monolithic" in claim 18 was thus erroneous, and the §102 rejection based on Vidal should be reversed for yet a second reason.

2. The Examiner Failed to Establish a *Prima Facie* Case of Obviousness of Claim 18 Based on Vidal

Similarly, the Examiner's § 103 rejection of claim 18 based on Vidal must be reversed, because there must be a showing of a suggestion or motivation to modify the teachings of Vidal to provide an orientation indicator as claimed by Applicant. *B.F. Goodrich,* 72 F.3d at 1582. Notably, Vidal does not contain a suggestion of any type of orientation indicator using those words or words of similar import. The word "orientation" is not to be found in the Vidal patent. There being no evidence of any suggestion or motivation to modify Vidal to provide an orientation indicator, the § 103 rejection of claim 18 based on the Vidal patent must be reversed.

D. The § 103 Rejection of Claim 18 Based on Johnson in View of Metcalfe Must Be Reversed

1. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness of Claim 18

The establishment of a *prima facie* case of obviousness requires, among other things, that the prior art, when combined, must teach or suggest all of the claim limitations. *Vaeck,* 947 F.2d at 493. The criteria is not satisfied by the Examiner's § 103 rejection based on Johnson in view of Metcalfe.

The Examiner asserts that "**[t]he difference** between the claimed subject matter and Johnson resides in a case for enclosing the at least one obturator". Office Action, p. 3 (emphasis added). The Examiner then cites Metcalfe for the proposition that it was known to provide a case for an instrument. *Id.*

The fundamental premise of the §103 rejection is erroneous, because several differences exist between claim 18 and Johnson. First, claim 18 calls for an obturator for use in endoscopic surgery. The Johnson patent, however, describes an obturator for use in an endodonic filler application, i.e. a root canal procedure. Johnson patent, Col. 1, ll. 62-63; FIG. 5. Second, claim 18 of this application calls for the obturator to have a distal end with a tip that is used either to cut or separate tissue.[1] The device disclosed in the Johnson patent has no such tip, because Johnson's device is designed to be inserted in a root canal 28 formed in a tooth (Johnson patent, FIG. 5) , and it appears that it would be virtually impossible to use the tip of Johnson's device to cut or to separate tissue in view of its size. Third, Johnson does not describe an orientation indicator which, as previously discussed, enables the user to determine by touch the relative position of the tip at the distal end of the obturator.

The Examiner's assertion that washer 22 and shaft 18 in Figures 1 and 2 of Johnson constitute an orientation indicator is meritless. The difference in diameter between washer 22 and shaft 18 does not provide the user any information about the orientation of the tip at the distal end of the obturator. Even if the difference in diameter between washer 22 and shaft 18 were somehow to provide any information about the orientation of tip 14, it would be impossible for this information to be determined by touch as required by claim 18. This is because no hand of a human being can fit within a human tooth to touch washer 22 and shaft 18. *See* FIG. 5 of Johnson.

Moreover, Johnson does not teach or suggest an obturator for use in endoscopic surgery, as required by claim 18 of this application. The size of Johnson's

[1] This limitation in claim 18 is not even discussed by the Examiner in the Office Action.

device is small, since it is used in a root canal procedure, and the device has no tip for cutting or separating tissue. Rather, the way that the device described in Johnson works is as follows: Filler material 26 is applied to the shaft portion 18 of the obturator by subjecting the filler material and obturator to elevated temperatures for a selected length of time. The filler material 26 securely adheres to the shaft 18 but is pliable for insertion into the root canal 28. (Col. 2, l. 62 - Col. 3, l. 3; FIG. 5.) When the obturator containing the filler material 26 is inserted in root canal 28, the stopper or washer 22 is axially moved from the position shown in FIG. 1 or FIG. 7 to the position shown in FIG. 5 to retain the filler material 26 in the canal. When the obturator has been inserted to the proper depth in the root canal, the shaft portion is severed and the handle 16, the unused position of shaft 18 and washer 22 are removed from the tooth.

Thus, the manner in which Johnson's device is constructed and the way that it is to be used evidence that Johnson's device is neither designed nor suitable for use in endoscopic surgery.

Based on the foregoing, the §103 rejection made by the Examiner is fundamentally flawed and must be reversed.

2. Substantial Reconstruction and Redesign of the Device of Johnson Patent Would Be Required For it to Be Used in Endoscopic Surgery

Clearly, any use of the device disclosed in Johnson as an obturator for endoscopic surgery would require a substantial reconstruction and redesign of the elements in Johnson, as well as a change in principle under which the device in Johnson

was designed to operate. Under these circumstances, the Examiner's use of the Johnson patent to make a § 103 rejection is erroneous. *Ratti,* 270 F.3d 813.

3. The § 103 Rejection Based on Johnson And Metcalfe is Based on Impermissible Hindsight Reconstruction

It is apparent from the foregoing that what the Examiner did in making the final rejection is to use applicant's invention as a template in attempting to piece applicant's invention together from the prior art without any suggestion in the prior art to do so. Such a procedure is the essence of hindsight reconstruction, *Dembiczak,* 175 F.3d at 999, and is improper as a matter of law. *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n,* 998 F2.d 1165 (Fed. Cir. 1993).

E. Dependent Claims 8 and 9 Define Patentable Subject Matter

The law is well-established that dependent claims are patentable if the independent claim from which they depend are patentable. *E.g. In re Fine,* 837 F.2d 1071, 1076 (Fed. Cir. 1988). Thus, the demonstrated patentability of independent claim 18 over the references cited by the Examiner establishes the patentability of dependent claims 8 and 9 over those references as a matter of law.

VIII. CONCLUSION

The Examiner's final rejection of claims 8, 9 and 18 of this application was erroneous. The § 102 rejection based on the Vidal patent was erroneous, because Vidal does not disclose either an orientation indicator or a monolithic structure as called by

claim 18. The Examiner has not made out a *prima facie* case of obviousness based on Vidal because there is not any suggestion, motivation or teaching to modify Vidal to include an orientation indicator.

The Examiner did not make out a *prima facie* case of obviousness based on the Johnson and Metcalfe patents. Johnson and Metcalfe, when combined, do not teach or suggest all of the limitations of claim 18. Moreover, there is no suggestion, motivation or teaching to make the combination which the Examiner made to reject claim 18. The device disclosed in Johnson is flatly unsuitable for use in endoscopic surgery, and any use of Johnson's device for that purpose would require a substantial redesign of and change in principle of operation of Johnson's device. The § 103 rejection is also erroneous because it is based on hindsight reconstruction.

The Examiner's final rejection must, therefore, be reversed, and such action is respectfully requested.

Respectfully submitted,

Date: NOV. 15, 2005

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IX. CLAIMS APPENDIX

8. The medical kit of claim 18, wherein said kit comprises three obturators, a first obturator having a cutting tip at its distal end, a second obturator having a substantially blunt tip at its distal end, and a third obturator having a tissue separating tip at its distal end.

9. The medical kit of claim 18, wherein at least one of said obturators is decorated with graphical and/or textural information for assisting the user in matching said obturator with a correspondingly sized trocar.

18. A medical procedure kit, comprising:

(a) at least one disposable, shield-less obturator for use in endoscopic surgery, each said obturator comprising (i) a proximal end where the obturator is grasped, (ii) a distal end having a tip which is used either to cut or to separate the tissue of a patient, (iii) a shaft between the proximal and distal ends, the proximal end and distal ends and the shaft being formed as a monolithic structure, and (iv) an orientation indicator located near the proximal end which enables a user to determine by touch the relative position of the tip at the distal end; and

(b) a case for enclosing said at least one obturator.